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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/765,380	01/26/2004	Rodney A. Perkins	017534-000740US	2521

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EXAMINER

MALLARI, PATRICIA C

ART UNIT	PAPER NUMBER
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3736

DATE MAILED: 06/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

6

<b>Office Action Summary</b>	<b>Application No.</b> 10/765,380	<b>Applicant(s)</b> PERKINS ET AL.	
	<b>Examiner</b> Patricia C. Mallari	<b>Art Unit</b> 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 29 April 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-4 and 14-18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 14-18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
- 1. ☐ Certified copies of the priority documents have been received.
  - 2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>4/2/04</u> . | 6) <input type="checkbox"/> Other: _____  |

***Election/Restrictions***

Applicant's election without traverse of Group I in the reply filed on 4/29/05 is acknowledged.

***Claim Objections***

Claim 1 is objected to because of the following informalities: on line 2 of claim 1, "said kit" should be replaced with "said system". Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 14-18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification fails to disclose a system wherein the sealing catheter carries a closure element comprising tissue adhesive, fibrin glue, cyanoacrylate, an occlusive balloon, self-expanding mesh, or a coil. While the specification briefly indicates that fibrin glues, cyanoacrylate, occlusive balloons, self-expanding meshes, and coils may be used to seal an air passage (lines 20-23 of p. 3 of the instant specification), such disclosure fails to indicate that the listed materials are carried by the sealing catheter, wherein the sealing catheter may be inserted through the lumen of the isolation/access catheter as claimed.

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Claims 14-18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. As indicated above, the specification fails to provide a thorough description of a system wherein any of tissue adhesive, fibrin glue, cyanoacrylate, an occlusive balloon, a self-expanding mesh, or a coil are carried by a sealing catheter and may be deployed by the sealing catheter, wherein such sealing catheter may be introduced through an isolation/access catheter, as claimed. The specification merely mentions, "other sealing methods include the use of tissue adhesives . . . occlusive balloons; . . . self-expanding meshes, coil" (lines 20-23, p. 3 of the instant specification) and describes a system wherein a partially hydrated collagen hydrogel plug is carried by and deployed by the sealing catheter (paragraph 51 of the instant specification).

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. 5,588,424 to Insler et al. Insler discloses a system comprising an isolation/access catheter having a proximal end, a distal end, an occlusion element 18 near the distal end, and at least one lumen 12, 14 extending therethrough (fig. 3; col. 3,

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lines 14-38 of Insler). A sealing catheter 16 has a proximal end, a distal end, and a closure element 32 carried by the sealing catheter (fig. 3; col. 3, line 65-col. 4, line 6 of Insler). The sealing catheter 16 may be introduced through the lumen 14 of the isolation/access catheter and the closure element may be deployed from the sealing catheter 16 (fig. 3; col. 3, line 65-col. 4, line 13 of Insler).

As to the language "for performing intraluminal lung volume reduction" on lines 1-2 of the preamble, the applicants should note that this is merely intended use language which cannot be relied upon to define over the prior art, as Insler teaches all of the claimed elements and their recited relationships. See *Ex parte Masham* 1647 2 USPQ 2<sup>nd</sup> and MPEP §2111.02. The system of Insler appears to be fully capable of being used for performing intraluminal lung volume reduction.

Regarding claim 2, the closure element 32 comprises a swellable plug (col. 3, line 67; fig. 3 of Insler).

Regarding claims 3 and 4, the isolation/access catheter includes at least two lumens 12, 14 extending therethrough (fig. 3; col. 3, lines 14-30 of Insler). With further regard to claim 4, the isolation/access catheter further includes a fiberoptic bronchoscope disposed to permit forward viewing, wherein a fiberoptic bronchoscope necessarily comprises a fiber optic scope and a light source (col. 4, lines 5-9 of Insler).

Regarding claim 16, the closure element 32 comprises an occlusive balloon (fig. 3; col. 4, lines 9-13 of Insler).

### ***Conclusion***

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The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US Patent No. 5,904,648 to Arndt et al

US Patent No. 5,803,080 to Freitag

US Patent No. 4,911,163 to Fina


US Patent No. 1,906,678 to Wappler

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia C. Mallari whose telephone number is (571) 272-4729. The examiner can normally be reached on Monday-Friday 10:00 am-6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Patricia Mallari  
Patent Examiner  
Art Uni 3736

  
MAX F. HINDENBURG  
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